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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Jacques Thilly

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EXAMINER

SMALLEY, JAMES N

ART UNIT

PAPER NUMBER

3781

MAIL DATE

DELIVERY MODE

11/23/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/524,886	Applicant(s) THILLY ET AL.	
	Examiner JAMES N. SMALLEY	Art Unit 3781	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 October 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-13 and 17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4 and 8-13 is/are rejected.
- 7) ☒ Claim(s) 2,5-7 and 17 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/24/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Response to Amendment

1. The indicated allowability of claims 1-2, 4-13 and 17 is withdrawn in view of the newly discovered reference(s) to Jansen et al. US 6,378,714. Rejections based on the newly cited reference(s) follow. Accordingly, this action is **Non-Final**.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1, 4 and 8-11 are rejected under 35 U.S.C. 102(e) as being anticipated by Jansen et al. US 6,378,714.

Examiner notes Jansen '714 was published on April 30, 2002, which is before Applicant's earliest priority date of August 16, 2002.

Regarding claims 1, 10-12, Jansen '714 teaches an elastomer closure part (32; taught to be formed of an elastomeric material in column 5, line 53) to seal a vial mouth opening (30), a clamp part (40) having an aperture therethrough (60), which exposes a portion of the stopper to the piercing member (42), a cover part (44) which has a segment (88) linked to the rest of the cover part (96) by a frangible link (98), and which comprises a snap-fit engagement in a peripheral wall (also located at 96; interacts with the clamp part rim (unlabeled; shown in figure 3).

Regarding claim 4, the frangible link is linked to the skirt wall, as shown in figure 2.

Regarding claims 8-9, the entire closure part is formed of an elastomer, and thus the upper part will be formed of a thermoplastic elastomer.

Regarding claim 9, the clamp is formed of thermoplastic material.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 12-13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jansen et al. US 6,378,714 in view of Py US 6,604,561.

Jansen '714 teaches all limitations substantially as claimed, but fails to teach filling the container with a needle piercing the stopper, and then sealing the opening with residual heat.

Py '561 teaches a method of filling a vial with a medication, in which a needle pierces a stopper, and then such opening is sealed upon removal of the needle with residual heat. In column 3, lines 19-28, the reference teaches the method is more sanitary, as the filling occurs after sealing.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of filling the container of Jansen '714, filling the container with a needle piercing the stopper, and then sealing the opening with residual heat, as taught by Py '561, motivated by the benefit of maintaining a higher level of sterility.

The Supreme Court in *KSR* reaffirmed the familiar framework for determining obviousness as set forth in *Graham v. John Deere Co.* (383 U.S. 1, 148 USPQ 459 (1966)), but stated that the Federal Circuit had erred by applying the teaching- suggestion-motivation (TSM) test in an overly rigid and formalistic way. *KSR*, 550 U.S. at ___, 82 USPQ2d at 1391. Specifically, the Supreme Court stated that the Federal Circuit had erred in four ways: (1) "by holding that courts and patent examiners should look only to the problem the patentee was trying to solve " (*Id.* at ___, 82 USPQ2d at 1397); (2) by assuming "that a person of ordinary skill attempting to solve a problem will be led only to those elements of prior art designed to solve the same problem" (*Id.*); (3) by concluding "that a patent claim cannot be proved

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obvious merely by showing that the combination of elements was obvious to try” (*Id.*); and (4) by overemphasizing “the risk of courts and patent examiners falling prey to hindsight bias” and as a result applying “[r]igid preventative rules that deny factfinders recourse to common sense” (*Id.*). In *KSR*, the Supreme Court particularly emphasized “the need for caution in granting a patent based on the combination of elements found in the prior art,” *Id.* at ___, 82 USPQ2d at 1395, and discussed circumstances in which a patent might be determined to be obvious. Importantly, the Supreme Court reaffirmed principles based on its precedent that “[t]he combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.” *Id.* at ___, 82 USPQ2d at 1395.

Furthermore, the Supreme Court issued rationales which support the conclusion of obviousness, and which can be found in the MPEP 2141(III). Under rationale (c) a device may be modified by a known process or technique applied to a similar device. It would thus be beneficial to apply the technique of Py '561 to the container of Jansen '714, motivated by the benefit of a higher level of sterility.

Allowable Subject Matter

6. Claims 2, 5-7, and 17 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

7. Applicant's arguments with respect to claims 1-2, 4-13 and 17 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAMES N. SMALLEY whose telephone number is (571)272-4547. The examiner can normally be reached on Monday - Friday 10 am - 7 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Stashick can be reached on (571) 272-4561. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Anthony Stashick/
Supervisory Patent Examiner, Art Unit
3781

/James N Smalley/
Examiner, Art Unit 3781